REMARKS

FORMAL MATTERS:

Claims 13-19 are pending after entry of the amendments set forth herein.

Claims 1-4 are canceled without prejudice.

New claims 13-19 have been added. Support for new claims 13-19 can be found in the claims as originally filed and throughout the specification at, for example:

Claim 13: original claims 1 and 8; Examples 1-5, and para. [0100] and [0101];

Claim 14: original Claim 2;

Claim 15: original Claims 3, 7, and 8;

Claim 16: original Claim 4;

Claim 17: para. [0134-0135]; and Examples 1-5;

Claim 18: Claim 10 of priority application JP-2002-383869, the disclosure of which was incorporated by reference at para. [0003].

Claim 19: para. [0134-0135]; and Examples 1-5.

Accordingly, no new matter has been added.

In view of the amendments above and the remarks put forth herein, reconsideration and allowance are respectfully requested.

PRIORITY

Applicants submit herewith the following:

- Certified copy of Japanese application # 2000-112699 as required by 35 U.S.C. 119 (b);
- Translated copy of Japanese application # 2002-327516;
- Translated copy of Japanese application # 2002-383869.

As such, Applicants request that the instantly pending claims be granted priority to the above applications.

The Office Action asserts that Claims 2 and 3 have been awarded the effective filing date of the instant application because the parent U.S. Application Serial No. 10/257,511 does not support the subject matter.

Although claims 2 and 3 have been canceled, Applicants submit that the subject matter and sequences referred to as SEQ ID NO's: 1 to 27088 are fully supported in Japanese application # 2002-327516 which has a priority date of September 28, 2002.

REJECTIONS UNDER §101 AND §112, ¶1

Claim 3 has been rejected under 35 U.S.C. §101, and under §112, ¶1, for allegedly lacking a specific utility. In particular, the Office Action alleges that the specification does not teach an association between the microsatellite markers of SEQ ID NO's: 1 and 2 and any specific phenotype or specific gene associated with a particular phenotype. This rejection is traversed as applied and as it may be applied to the presently pending claims.

Without acquiescing to the correctness of the grounds of the rejections as applied, Claims 3 has been canceled, thereby rendering this rejection moot.

As to the pending claims, these claims are directed to a new method of association analysis in which susceptible genes for multifactorial or complex diseases are identified by genome-wide screening. In order to identify the susceptible genes for complex diseases, the sequences represented by SEQ ID NOS: 1 to 27088 are not used separately but as a single set of 27088 sequences, with each containing at least one microsatellite marker. Thus each of the sequences represented in claim 3 should not be viewed as a distinct invention, but rather as part of a gene mapping method using a seat of sequence of SEQ ID NOS: 1 to 27088.

As described in the specification (see, e.g., para. [0007]), analysis becomes difficult in terms of tremendous time and labor when there are multiple microsatellite genetic polymorphism markers used. In contrast, if too few markers are used, no correlation can be made and thus causative genes may be overlooked. The claimed invention solves this problem by providing a gene mapping method which can be used for the identification of susceptibility genes for not only a single disease by conventional linkage analysis, but also for the identification of susceptibility genes of multifactorial diseases through a genome-wide screening by association analysis.

Thus, the methods of the invention are not limited linking a known disease associated with microsatellite markers, as the Office Action seems to require for utility. Instead, the methods encompass identifying new pathogenic genes and regions of such genes associated with a disease (a human phenotype associated with a genetic factor). Similar to methods of screening agents against a target to identify their activity as a drug, the present methods provide methods for screening to identify genes and gene fragments associated with a disease.

Accordingly this rejection may be withdrawn.

REJECTIONS UNDER §103(A)

Barcellos et al. (Am. J. Hum. Genet., vol. 61, pages 734-747) in view of Kamb (US Patent No. 5,683,880)

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Barcellos et al. in view of Kamb.

As noted above, Claims 1 and 2 have been canceled, thereby rendering this rejection moot. However, Applicants wish to present arguments with respect to newly added Claims 13-19.

According to MPEP § 2142:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

For the reasons set forth below, there is no teaching or suggestion in the combination of cited references of all of the elements of the claimed invention. Specifically, the references do not teach or suggest a method of genome-wide screening with a single set of 27088 sequences, let alone screening with the specific sequences represented in SEQ ID NO's: 1 to 27088.

Barcellos et al. discloses a method of detecting disease loci by screening with microsatellite markers. However, Barcellos only employs four microsatellite markers (D6S105, F14A1, TH and MBP; see page 736, col. 1, last paragraph). If such a limited number of markers were used, the number of diseases detectable using the disclosure of Barcellos et al. would be greatly restricted. In Barcellos et al. it is necessary to know the specific regions of the genome sequence where polymorphic microsatellites exist that would be useful as a marker of a susceptibility gene.

In contrast, the present methods allow for screening the entire genome, and thus avoid the limitations of a screening based on the disclosure of Barcellos et al. The present invention allows effective genetic correlation analysis throughout a genome sequence, regardless of race and genetic relatedness, since the microsatellites of SEQ ID NOS:1 to 27088 containing genetic polymorphisms are used. The polymorphisms represented by these sequences are shared by 95% or more of all races, thus avoiding the need for any family-based analysis as disclosed in Barcellos et al.

The Office Action further cites Kamb for teaching that microsatellite repeats are located in the human genome at intervals of approximately 100 kb. However, nowhere does the reference teach or suggest a method of genome-wide screening which involves the sequences represented by SEQ ID NO's: 1 to 27088 as a single set of 27088 sequences, with each containing at least one microsatellite marker. As such, Kamb fails to make up for the deficiency of Barcellos et al.

Therefore, the combination of references fails to teach each and every element of the present claims. Accordingly, this rejection may be withdrawn.

Barcellos et al. (Am. J. Hum. Genet., vol. 61, pages 734-747) in view of Kamb (US Patent No. 5,683,880) and further in view of Braun (Genomics, vol. 46, pages 18-23)

Claim 4 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Barcellos et al. in view of Kamb and further in view of Braun.

As noted above, Claim 4 has been canceled, thereby rendering this rejection moot. However, Applicants wish to present arguments with respect to newly added Claims 13-19.

As set forth above, Claims 13-19 are patentable over Barcellos et al. in view of Kamb because the combined teachings of the cited references fail to disclose each and every element of the present invention. In particular, the combination of references do not teach a method of genome-wide screening which involves the sequences represented by SEQ ID NO's: 1 to 27088 as a single set of 27088 sequences, with each containing at least one microsatellite.

According to the Office Action, Braun was cited for teaching that microsatellite markers can be analyzed by using a probe target disk and a mass spectrometer. As such, Braun fails to cure the deficiencies of the disclosures of Barcellos or Kamb.

Applicants submit that the presently pending claims are not obvious under 35 U.S.C. § 103(a) over Barcellos in view of Kamb and Braun because none of the references teach a method of genome-wide screening which involves the sequences represented by SEQ ID NO's: 1 to 27088 as a single set of 27088 sequences, with each containing at least one microsatellite, Accordingly, this rejection may therefore be withdrawn.

Kamb (US Patent No. 5,683,880)

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamb.

As noted above, Claims 1 and 2 have has been canceled, thereby rendering this rejection moot. However, Applicants wish to present arguments with respect to newly added Claims 13-19.

As discussed above, Kamb discloses that microsatellite repeats are located in the human genome at intervals of approximately 100 kb. However, nowhere does the reference teach or suggest a method of genome-wide screening which involves the sequences represented by SEQ ID NO's: 1 to 27088 as a single set of 27088 sequences. Moreover, Kamb does not disclose which microsatellites are polymorphic. Each of the microsatellite markers of SEQ ID NOS: 1 to 27088 are polymorphic.

For at least these reasons, Kamb fails to teach or suggest each and every element of the presently pending claims. Accordingly, this rejection may be withdrawn.

Kamb (US Patent No. 5,683,880) in view of Braun (Genomics, vol. 46, pages 18-23)

Claim 4 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamb in view of Braun.

As noted above, Claim 4 has been canceled, thereby rendering this rejection moot. However, Applicants wish to present arguments with respect to newly added Claims 13-19.

As set forth above, Claim 4 is patentable over Kamb because the reference fails to disclose each and every element of the present invention. In particular, Kamb does not teach a method of genome-wide screening which involves the sequences represented by SEQ ID NO's: 1 to 27088 as a single set of 27088 sequences, with each containing at least one microsatellite genetic polymorphism marker.

Braun was cited for teaching that microsatellite markers can be analyzed by using a probe target disk and a mass spectrometer. Braun fails to cure the deficiency of the disclosure of Kamb. As such, the combination of references do not render the presently pending claims obvious.

Accordingly, this rejection may be withdrawn.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number WING-003CIP.

Respectfully submitted,
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Enclosures:

- Certified copy of Japanese application # 2000-112699
- Certified translated copy of Japanese application # 2002-327516
- Certified translated copy of Japanese application # 2002-383869

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